



TechLaw
Quality & Integrity

Amendment to the Responses and Corrective Actions for:

**Quality Assurance Support for the Libby Asbestos Site:
Summary Asbestos On-Site Audit Conducted May 22-23, 2012 of the
TechLaw, Inc. ESAT Region 8 TEM and PLM Asbestos Analytical Laboratories**

This Report Prepared By:

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2-28-13

Date

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02/28/13

Date

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1.0 ON-SITE AUDIT SUMMARY

An audit of TechLaw's Environmental Services Assistance Team Contract (ESAT) Region 8 Transmission Electron Microscopy (TEM) and Polarized Light Microscopy (PLM) asbestos analytical laboratories was conducted on May 22-23, 2012. The audit was conducted in support of the United States Environmental Protection Agency (EPA) Libby Asbestos Superfund Site activities and involved an evaluation of the laboratory's ability to process samples and data in accordance with the EPA-provided Libby-specific guidance documents. The audit was conducted by Dania Zinner, Remedial Project Manager, EPA Region 8 and Michael Lenkauskas, CQA, Lead Auditor, Shaw Environmental, Inc. (Shaw) as part of the Quality Assurance Technical Support Program (QATS).

The audit consisted of technical and evidentiary aspects. The technical part of the audit involved an evaluation of the laboratory facilities, personnel, and capabilities to process samples and data as described in the Libby-specific guidance documents. Processes evaluated included sample receiving, sample storage, sample tracking, sample preparation, sample analysis, data review, and test report assembly. Laboratory instrumentation and equipment were inspected for proper maintenance and calibration, and laboratory personnel were interviewed to determine proficiency in their assigned responsibilities. Specific instrumentation and areas inspected included sample preparation, PLM, TEM, and the laboratory's capability to provide the required hard copy and electronic deliverables.

The evidentiary part of the audit involved an assessment of laboratory documentation for accuracy, completeness, and defensibility. The laboratory Standard Operating Procedures (SOPs) and other quality documents were assessed for availability and accuracy to observed procedures, and instrument calibration and maintenance logbooks were reviewed for completeness, traceability, and accuracy. During the course of the audit, the Libby-Specific Asbestos Laboratory On-Site Audit Checklist was completed by the QATS Auditor.

2.0 EPA RESOLUTION REPORT SUMMARY

The 2012 Summary Asbestos On-site Audit Report was submitted to TechLaw, Inc. ESAT Region 8 in Golden, Colorado on June 26, 2012 following EPA approval. The audit report consisted of 11 comments describing 12 deficiencies. ESAT Region 8 provided a response on July 31, 2012. Of the 11 comments, ESAT Region 8 agreed with eight (Comments 1, 2, 3, 6, 7, 8, 10, and 11) and disagreed with three (Comments 4, 5, and 9). The audit report comments in question, numbered as they were in the report, are listed below. Following each comment is the ESAT Region 8 response, the rationale used by QATS in assigning the defect, and the EPA resolution, and the ESAT Region 8 Amendment to the original response.

2.1 Audit Report Comment #4

Finding/Corrective Action: The laboratory uses a syringe with Teflon tubing rather than disposable pipettes to extract the necessary suspension volumes to prepare secondary filters for the indirect preparation procedure described in the Libby-specific SOP. While the laboratory has generated data to determine the volume lost during transfer and the effectiveness of decontamination between samples for this alternative technique, they have not determined the potential for fibers to adhere to the syringe and tubing. The requirement to use disposable pipettes to measure suspension volumes is described in Sections 3.0, 4.1.20, and 4.2.14 of the Libby-specific SOP for the Indirect Preparation of Air and Dust Samples for TEM Analysis (SOP

EPA-Libby-08). Recommended Corrective Action – Use disposable pipettes to measure the aliquots of the filter suspension applied to the secondary filters prepared during the indirect preparation procedure. *Audit Checklist No. 6.14.1*

ESAT Region 8 Response (07/31/2012): Statistical data of the technique we use to bring samples to a specific volume and obtain aliquots for indirect sample preparations has been determined and included in our estimation of analytical uncertainty (TEM-02.00 Draft). The transfer loss has been determined to be $-0.09\text{ml} \pm .31\text{ml}$ at the 95% confidence interval. The potential for fibers to adhere to the syringe and Teflon tubing has not been further determined for our technique; however, it has not been determined for the recommended corrective action either as described in Sections 3.0, 4.1.20 and 4.2.14 of SOP EPA-Libby-08, the Libby-specific SOP for the Indirect Preparation of Air and Dust Samples for TEM Analysis. In response to the audit finding, ESATR8 has petitioned to purchase a 1 to 10 ml adjustable volume Eppendorf pipette with disposable tips. If the purchase is approved, ESAT will discontinue use of the syringes with tubing for indirect preparation and begin using the pipette with disposable tips. ESAT TEM staff cannot take anymore action on this item until they are authorized to purchase the pipette.

QATS Rationale for Assigning the Defect (12/24/2012): The laboratory's response does not include a contingency plan should their request to purchase the necessary equipment be rejected. It only states that they will use the pipetting equipment described in the SOP "if" the purchase is approved. The laboratory needs to indicate whether or not the purchase request for the necessary equipment has been approved or to state the laboratory's contingency plan in the event it has not.

EPA Resolution is requested.

EPA Resolution (01/17/2013): EPA would like the laboratory to use a pipette with disposable tips. EPA will approve the purchase request for this equipment.

ESAT Region 8 Amendment to the Original Response (02/28/2013): *We have discontinued use of the syringes with Teflon tubing technique and are now using a 1-10ml adjustable volume Eppendorf pipette.*

2.2 Audit Report Comment #5

Finding/Corrective Action: Indirect preparation sample suspensions are not adjusted to a pH range of 3-4 with a 10% solution of glacial acid as required by the Libby-specific SOP. The pH is adjusted to destroy any biological growth; however, the analysts explained that since the laboratory water is treated with ultra-violet (UV), any bacteria should have been destroyed. The requirement to adjust the pH of indirect preparation suspensions to a pH range of 3-4 is described in Sections 4.1.16 and 4.2.8 of the Libby-specific SOP for the Indirect Preparation of Air and Dust Samples for TEM Analysis (SOP EPA-Libby-08). Recommended Corrective Action – In order to minimize/prevent biological growth, which can interfere with fiber detection and/or identification during TEM analysis, ensure that sample suspensions are adjusted to a pH range of 3-4 with a 10% glacial acetic acid solution. *Audit Checklist No. 6.8.3.3.1*

ESAT Region 8 Response (07/31/2012): The reason for performing pH adjustment during indirect preparation is provided in ASTM D5755, not in SOP EPA-Libby-08. The purpose of reducing the pH to 3 or 4 is to limit microbial growth, which in the experience of the ESAT TEM

staff, does not work. pH affects regulation of protons and ions and solubility of substances that some bacteria and fungi need. In fact, some bacteria are acidophilic. The EPA Region 8 laboratory facility has a water treatment process in which de-ionized water is treated with UV. Sample suspensions are done with UV treated water, and therefore, ESATR8 contests that that we need to adjust pH to limit microbial growth because microbes cannot grow when they have been destroyed. The EPA Region 8 Chemical Hygiene Plan (CHP) prohibits keeping flammables (acetone) in the same hood as acids and the ESAT TEM Lab is required to abide by the CHP. The chemical fume hood in Room D123 (TEM Sample Prep Room) is the only place ESAT has to store the chemical reagents that are in current use for TEM prep. Libby SOP EPA-Libby-08 needs to be revised to allow the option to not use acetic acid if UV-treated de-ionized water is used for indirect sample preparation.

QATS Rationale for Assigning the Defect (12/24/2012): Although the Audit Team disagrees with the laboratory that the referenced SOP needs to be revised, this does not change the fact that their current procedure deviates from the project-specific procedure and should, at a minimum, be addressed in a laboratory-specific Laboratory Modification to document this deviation.

EPA Resolution is requested.

EPA Resolution (01/17/2013): EPA agrees that this deviation should be documented in a laboratory-specific Laboratory Modification.

ESAT Region 8 Amendment to the Original Response (02/28/2013): *The recommended corrective action to use 10% acetic acid would bring us into non-compliance with the EPA Region 8 Laboratory Chemical Hygiene Plan, Section 6.6 (see Attachment A). A Laboratory Modification Form documenting non-use of acetic acid by ESAT Region 8 is provided as Attachment B for review. Air and dust samples submitted to ESAT Region 8 that are suitable for indirect preparation will be prepared by the indirect-ashed technique, which will remove any organic growth during the plasma ashing step.*

2.3 Audit Report Comment #9

Finding/Corrective Action: The laboratory is not currently performing the PLM analysis of fine ground soil samples as described in the Libby-specific SOP. One analyst described collecting the five random slide mounts prior to performing the fiber pick procedure. A second analyst combined (composited) five random samples from which they prepared the required five slides mounts. Both of these practices are deviations from SOP SRC-Libby-03 as currently written. The requirement that the laboratory supervisor ensure that all analyses are performed in accordance with the SOP and identify and take appropriate action to address any deviations is described in Section 3.1 of the Libby-specific SOP for the Analysis of Fibers in Soil by PLM (SRC-Libby-03, Rev. 2). Recommended Corrective Action – Ensure that all analyses are performed in accordance with the procedures described in the Libby-specific SOP for the Analysis of Fibers in Soil by PLM. *Audit Checklist Nos. 8.11.3.1 and 8.14.1*

ESAT Region 8 Response (07/31/2012): Regarding fiber picks, all analysts at ESAT currently follow the proper procedures. The entire sample is examined under the stereoscope, and a fiber pick is performed if suspect fibers are observed. Regardless if fibers are found and a fiber pick mount is made, the sample is agitated and reviewed a second time under the stereomicroscope. If a fiber pick mount was made during the first un-agitated examination, a

second mount is not necessary; multiple mounts may be made at the analyst's discretion, but they are not required. What is required is that the sample is examined in its entirety twice; once in its homogeneous state, and once after agitation (in an inhomogeneous state). Sections 13.1.5, 13.1.6, 13.1.8, 13.3, and 13.4.1 of SRC-LIBBY-03, Revision 3 have been revised to more clearly explain these procedures.

QATS Rationale for Assigning the Defect (12/24/2012): At the time of the on-site audit, the laboratory was operating under Revision 2 of SOP SRC-LIBBY-03. This SOP has since been revised to address deviations from the SOP that were observed at the time of the audit. QATS requests that the laboratory revise their laboratory response to reflect the subsequent revisions to the SOP that have been made to address these deviations.

EPA Resolution is requested.

EPA Resolution (01/17/2013): EPA agrees that the laboratory should revise their response to reference the updated SOP which has addressed these deviations.

ESAT Region 8 Amendment to the Original Response (02/28/2013): *The QATS rationale and EPA requested resolution state that we should revise our response to reflect the revisions to the SOP that were made to address the deviations described in comment 9. Our original response stated that Sections 13.1.5, 13.1.6, 13.1.8, 13.3, and 13.4.1 of SRC-LIBBY-3, Revision 3 (the newest revision) were revised to include more detail and enhance laboratory procedures, and these revised pages were included in Attachment J of our original response. In addition, all analysts were reminded to follow the SOP as written. Each analyst signed an acknowledgment form indicating that they have read and understand the latest revisions to the Libby-specific SOPs (see Attachment C).*

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Attachment A

EPA Region 8 Laboratory Chemical Hygiene Plan, Section 6.6

6.4 Laboratory Security

All visitors to the lab facility are required to sign in at the front desk.

Only personnel with a genuine business need to be in laboratories should enter laboratories. CSL-3 laboratories or materials requiring a health and safety research protocol must be locked when not in use.

No additional restrictions exist for CSL-1 & 2 laboratories.

Signage clearly identifying CSL-3 & 4 laboratories is required. Contracted housekeeping will not enter CSL-3 & 4 laboratories unless escorted or upon request.

6.5 Laboratory Tours

Tour groups should be limited to CSL 1 & 2 laboratories. If CSL-3 laboratories must host tours then the materials requiring the protocol must be locked prior to visitor's entry. If CSL-4 laboratories must host tours then visitors must be approved by the Safety Office. All visitors must comply with applicable PPE requirements.

6.6 Chemical Selection

Prior to conducting laboratory research involving hazardous materials, it is essential for employees to determine if substitution of materials with less hazardous substances is possible. The Safety Office must approve new chemicals prior to purchase to ensure the facility is capable of disposing of any waste, and to maintain quantities of materials below certain threshold reporting limits. Laboratory personnel must evaluate new products for compatibility with existing chemicals and equipment, and compatibility with existing ventilation systems. Chemicals should be chosen based on the least toxicity and availability of waste disposal outlets.

6.7 Personal Hygiene

Hand washing with soap and water must be performed immediately following removal of gloves and other PPE. When hand washing facilities are not available, antiseptic hand cleansers or antiseptic towelettes may be used until proper hand washing is accomplished. This step is an especially important function to perform before leaving the laboratory. Use mild detergents when washing exposed skin surfaces. Never wash with solvents or other chemicals that may cause adverse effects.

6.8 Appropriate Behavior

Practical jokes and horseplay have no place within a laboratory. They lead to accidents and injuries. Running through corridors is strictly prohibited.

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Attachment B

Laboratory Modification Form LB-000091



Request for Modification
to
Laboratory Activities
LB-000091

Instructions to Requester: E-mail form to contacts at bottom of form for review and approval.

All Labs Applicable Forms – copies to: EPA LC, QATS contractor, All Project Labs

Individual Labs Applicable Forms – copies to: EPA LC, QATS contractor, Initiating Lab

Method (circle all applicable):

TEM-AHERA

TEM-ISO 10312

PCM-NIOSH 7400

EPA/600/R-93/116

ASTM D5755

TEM 100.2

SRC-LIBBY-03

SRC-LIBBY-01

NIOSH 9002

Other: _____

Requester: Douglas Kent

Title: Senior Asbestos Microscopist

Company: TechLaw ESAT Region 8

Date: February 27, 2013

Original Requester: N/A

Original Request Date: N/A

Description of Modification:

Addition of a 10% solution of glacial acetic acid to the aqueous suspension during indirect sample preparation to adjust the pH to 3-4, as specified in section 4.1.16 of SOP EPA-Libby-08, "Indirect Preparation of Air and Dust Samples for TEM Analysis," is not practiced at the ESAT Region 8 TEM Laboratory. All indirect sample preparations at the ESAT Region 8 TEM Laboratory will be performed by the indirect-ashed procedure.

Reason for Modification:

Section 6.6 of the USEPA Region 8 Golden Laboratory Chemical Hygiene Plan states that, "Prior to conducting laboratory research involving hazardous materials, it is essential for employees to determine if substitution of materials with less hazardous substances is possible... Chemicals should be chosen based on the least toxicity and availability of waste disposal outlets." Acetone, which is flammable, is stored in the chemical fume hood in Room D123 (TEM Sample Preparation Lab) at the EPA Region 8 Laboratory and the fume hood is the only place available in Room D123 to keep chemicals in current use. Flammables and acids should be segregated, and the only liquid waste stream available in Room D123 is for disposal of acetone. As indicated in the ASTM D5755 method, the purpose of adding acetic acid is to avoid problems associated with bacterial and fungal growth. However, all de-ionized water at the Region 8 Lab is treated with ultraviolet light prior to use to control organic growth, and any organic growth in the sample is removed during plasma ashing. Based on this, laboratory staff have determined that acetic acid is redundant and have removed it from the preparation process to keep the ESAT Region 8 TEM Lab in compliance with the Chemical Hygiene Plan.

Potential Implications of this Modification:

None.

Laboratory Applicability (circle one): **All** **Individual(s)** ESAT Region 8

This laboratory modification is (circle one): **NEW** **APPENDS to** _____ **SUPERCEDES** _____

Duration of Modification (circle one):

Temporary

Date(s): _____

Analytical Batch ID: _____

Temporary Modification Forms – Attach legible copies of approved form with all associated raw data packages

Permanent

(Complete Proposed Modification Section)

Effective Date: February 27, 2013

Permanent Modification Forms – Maintain legible copies of approved form in a binder that can be accessed by analysts.

Proposed Modification to Method (attach additional sheets if necessary; state section and page numbers of method when applicable):
See above.

REFERENCES

ASTM International, 2009. ASTM D5755-09, Standard Test Method for Microvacuum Sampling and Indirect Analysis of Dust by Transmission Electron Microscopy for Asbestos Structure Number Surface Loading.

Ron Mahoney and Ed Cahill, EMSL Analytical, Inc., 2007. SOP EPA-Libby-08, Indirect Preparation of Air and Dust Samples for TEM Analysis

United States Public Health Service, Division of Federal Occupational Health, August 2008. USEPA Region 8 Golden Laboratory Chemical Hygiene Plan.

Data Quality Indicator (circle one) – Please reference definitions below for direction on selecting data quality indicators:

Not Applicable

Reject

Low Bias

Estimate

High Bias

No Bias

DATA QUALITY INDICATOR DEFINITIONS:

Reject - Samples associated with this modification form are not useable. The conditions outlined in the modification form adversely affect the associated sample to such a degree that the data are not reliable.

Low Bias - Samples associated with this modification form are useable, but results are likely to be biased low. The conditions outlined in the modification form suggest that associated sample data are reliable, but estimated low.

Estimate - Samples associated with this modification form are useable, but results should be considered approximations. The conditions outlined in the modification form suggest that associated sample data are reliable, but estimates.

High Bias - Samples associated with this modification form are useable, but results are likely to be biased high. The conditions outlined in the modification form suggest that associated sample data are reliable, but estimated high.

No Bias - Samples associated with this modification form are useable as reported. The conditions outlined in the modification form suggest that associated sample data are reliable as reported.

Technical Review: _____ Date: _____
(Laboratory Manager or designate)

Project Review and Approval: _____ Date: _____
(USEPA: Project Manager or designate)

Approved By: _____ Date: _____
(USEPA: Technical Assistance Unit Chief or designate)

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Attachment C

**Employee Acknowledgment Forms for SOPs SRC-LIBBY-03, Revision 3
and SRC-LIBBY-01, Revision 3**

I acknowledge that I have read and understand Standard Operating Procedure SRC-LIBBY-03, *Analysis of Asbestos Fibers in Fine Soil by Polarized Light Microscopy*, Revision 3, dated July 27, 2012.

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I acknowledge that I have read and understand Standard Operating Procedure SRC-LIBBY-01, *Qualitative Estimation of Asbestos in Coarse Soil by Visual Estimation Using Stereomicroscopy and Polarized Light Microscopy*, Revision 3, dated September 19, 2012.

Date

02/26/13

02/27/13

2/27/13

02/26/13

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2/26/13